ST/20D

ChM®

RADIAL HEAD PROSTHESIS

- *IMPLANTS*
- *INSTRUMENT SET 40.5231.000*
- *SURGICAL TECHNIQUE*

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SYMBOLS DESCRIPTIONS

	Caution - pay attention to the particular proceeding.
	Perform the activity with X-Ray control.
	Information about the next stages of the proceeding.
	Proceed to the next stage.
	Return to the specified stage and repeat the activity.
	Before using the product, carefully read the Instructions for Use supplied with the product. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.
	The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

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I. INTRODUCTION

The radial head is an essential anatomical and biomechanical element of the elbow joint. Significant restriction of elbow joint movement can be a reason of high percentage of disability especially for patients who have professions requiring precise movements.

In the case of multifragmental radial head fracture, radial head resection is still performed, but many complications are observed after this operation.
The indication for radial head replacement is a multifragmental, comminuted fracture of the radial head where stable osteosynthesis is not possible.

The presented prostheses are made of cobalt alloy *(in accordance with ISO 5832)*, UHMWPE polyethylene *(in accordance with ISO 5834)* and PEEK OPTIMA® Wear Performance *(in accordance with ISO 10993-1)*. Compliance with the requirements of Quality Management Systems ISO 9001, EN ISO 13485 and the requirements of Directive 93/42/EEC concerning medical devices guarantee high quality of the offered implants.

Implants and the instrument set have been developed in cooperation with Professor S. Pomianowski, Head of the Department of Traumatology and Orthopaedics, Postgraduate Medical Center in Otwock.

System for radial head replacement consists of:

- implants,
- instrument set,
- instructions for use and surgical techniques.

The radial head prosthesis is a bipolar implant; the stem is connected to the head as a socket joint, which enables the prosthesis head to rotate and tilt 15° against the stem axis in both directions. Total range of tilting is 30°.

The prosthesis stem has a collar which should rest against a stump of the radial neck which has been cut during surgery.

The prosthesis head has convex, *"barrel-shaped"* exterior surface to contact concave surface of the radial notch of the ulna. From above the surface is concave to contact convex shape of the humerus capitulum.

II. INDICATIONS AND CONTRAINDICATIONS FOR RADIAL HEAD REPLACEMENT

II.1. INDICATIONS

Indications for the radial head replacement in the case of comminuted fracture *(Type III according to Mason Classification)* are the following coexisting injuries:

- dislocation of the elbow joint together with radial head fracture *(Type IV)*;
- injury of the medial collateral ligament;
- injury of the lateral collateral ligament;
- Monteggia type injury with the olecranon fracture and the radial head fracture;
- fracture of the major part of the coronoid process *(Types II and III)*;
- coexisting injury of the distal radioulnar joint *(Essex-Lopresti type)* or injury of the interosseus membrane;
- as a combination of the above - complex injury and instability.

II.2. CONTRAINDICATIONS

The conditions mentioned below are considered contraindications for implantation of radial head prosthesis:

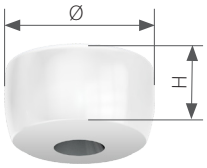
- damage to articular cartilage of the humeral head,
- arthritis, even as a chronic inflammation of the synovium.

III. IMPLANTS

Radial head prosthesis consists of:

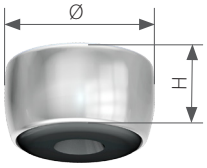
Solid head of radial head prosthesis

	Catalogue no.		
H [mm]	Ø20	Ø22	Ø24
10	7.3696.010	7.3697.010	7.3698.010
12	7.3696.012	7.3697.012	7.3698.012
14	7.3696.014	7.3697.014	7.3698.014

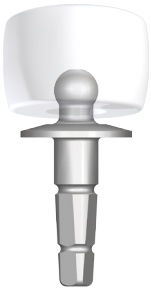


Modular head of radial head prosthesis

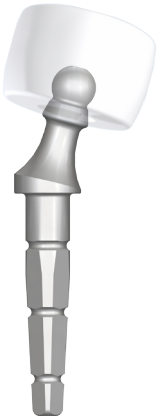
	Catalogue no.		
H [mm]	Ø20	Ø22	Ø24
10	4.3692.010	4.3693.010	4.3694.010
12	4.3692.012	4.3693.012	4.3694.012
14	4.3692.014	4.3693.014	4.3694.014



Stem of radial head prosthesis [4.3690.000]



Angular stem of radial head prosthesis *(reconstructive)* [4.3691.000]



The radial head prosthesis components are packed in separate sterile packages and are put together during surgical procedure.

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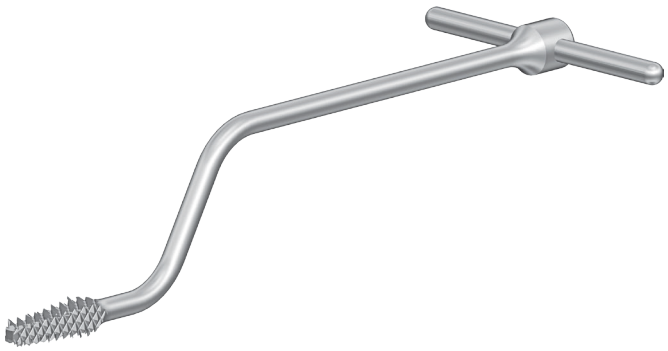
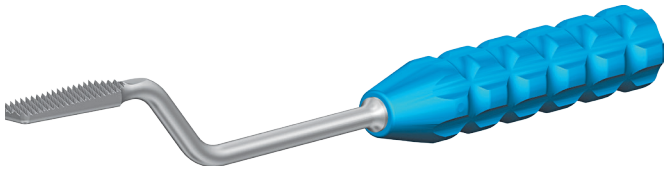
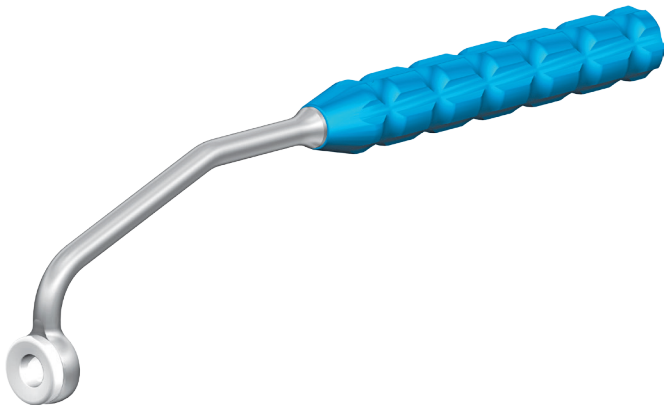
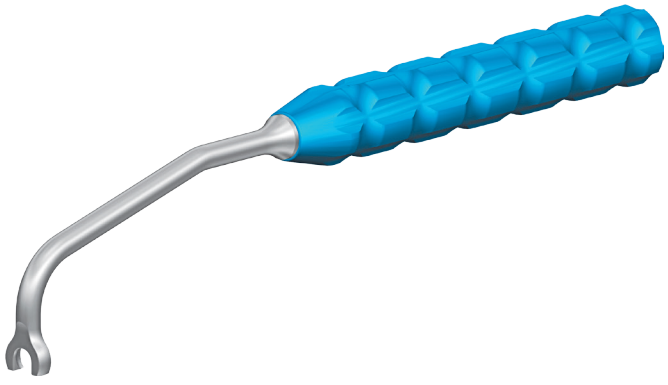
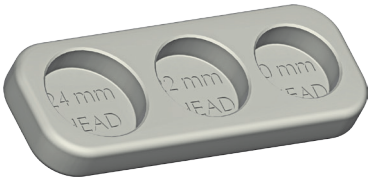
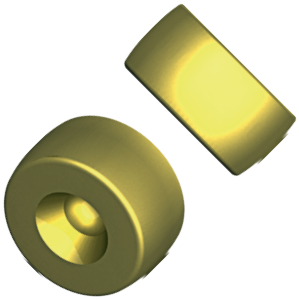
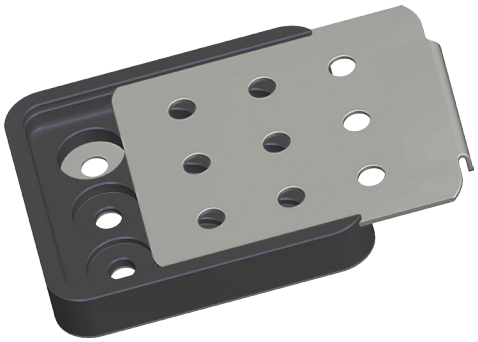
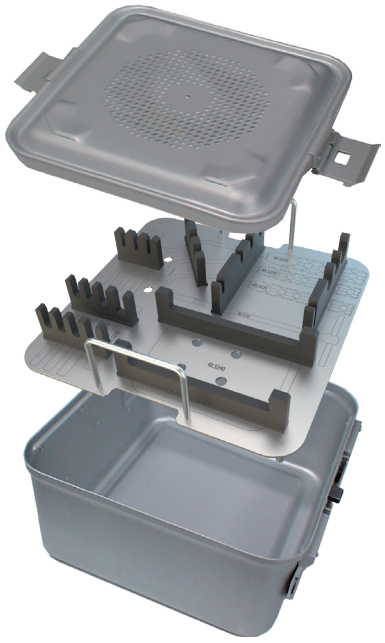
IV. INSTRUMENTS

For radial head replacement and radial head prosthesis removal, the instrument set **[40.5231.000]** shall be used.

The instrument set comprises the following devices:

	Name	Catalogue no.	Pcs.
	Rasp for radial bone	40.5232.000	1
	Rectangular curved file	40.5233.000	1
	Rhb prosthesis stem impactor	40.5234.000	1
	Rhb prosthesis stem holder	40.5235.000	1
	Radial head bone trial	40.5236.000	1

	Name	Catalogue no.	Pcs.
	Rhb head prosthesis trial 20 H10	40.5237.010	1
	Rhb head prosthesis trial 20 H12	40.5237.012	1
	Rhb head prosthesis trial 20 H14	40.5237.014	1
	Rhb head prosthesis trial 22 H10	40.5238.010	1
	Rhb head prosthesis trial 22 H12	40.5238.012	1
	Rhb head prosthesis trial 22 H14	40.5238.014	1
	Rhb head prosthesis trial 24 H10	40.5239.010	1
	Rhb head prosthesis trial 24 H12	40.5239.012	1
	Rhb head prosthesis trial 24 H14	40.5239.014	1
	Stand for head prosthesis trials	40.5240.000	1
	Resection guide 10	40.5242.010	1
	Resection guide 12	40.5242.012	1
	Resection guide 14	40.5242.014	1
	Perforated aluminum lid 1/2 306x272x15mm gray	12.0751.200	1
	Stand insert rhb prosthesis	40.5249.100	1
	Container with solid bottom 1/2 306x272x85mm	12.0751.100	1

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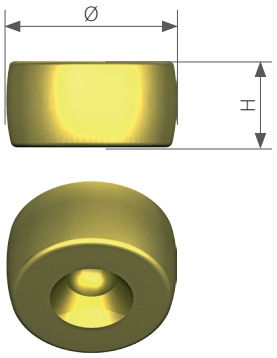
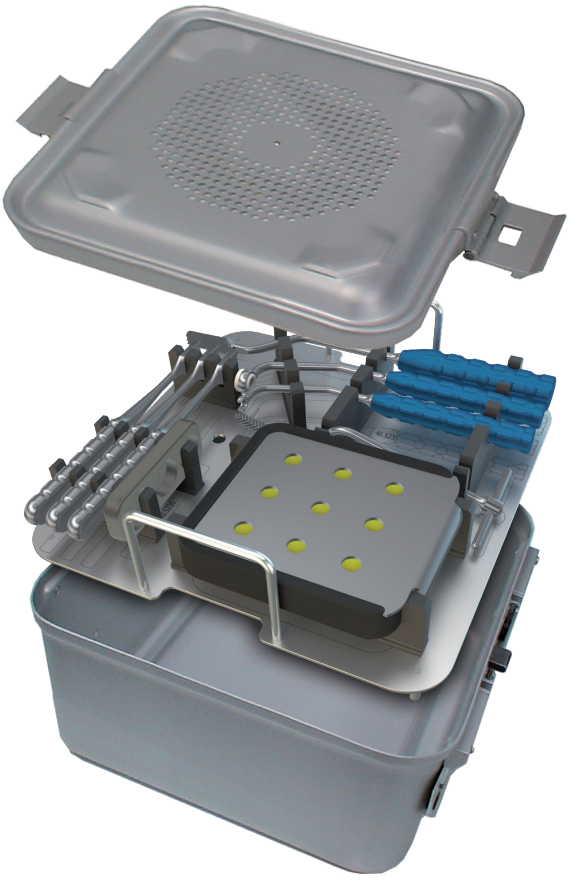
Rhb head prosthesis trial

Ø [mm]	H [mm]	Catalogue no.
20	10	40.5237.010
20	12	40.5237.012
20	14	40.5237.014
22	10	40.5238.010
22	12	40.5238.012
22	14	40.5238.014
24	10	40.5239.010
24	12	40.5239.012
24	14	40.5239.014



Resection guide *(in the case of using the stem [4.3690.000])*

Solid head of radial head prosthesis H [mm]	Catalogue no.
10	40.5242.010
12	40.5242.012
14	40.5242.014



Instruments for radial head prostheses
[40.5231.000]

V. SURGICAL TECHNIQUE

Surgical technique has been developed in cooperation with Professor S. Pomianowski, Head of the Department of Traumatology and Orthopaedics, Postgraduate Medical Center in Otwock. The experience of the medical center as well as the experience of the surgeon are the most important aspects when selecting the treatment method.

V.1. SURGICAL APPROACH TO THE HUMERORADIAL JOINT

Operation should be performed in Esmarch's clamp.Anterior-lateral operative approach should be used.
Straight skin incision is made 1cm above the lateral epicondylus of the humerus and 2cm distal from palpable radial head.

Incision is 8-10cm long. It is advised to mark osseous points: the lateral epicondylus of the humerus, the head of the radius, and the top of the olecranon. After skin and subcutaneous tissue incision, expose the fascia *(pic. a)*. After it has been cut, partially release the attachment of the brachioradialis muscle for approx. 2cm. Then go forward to the radiohumeral joint between both carpi radialis extensors muscles and common extensor digitorum tendon. While making the approach, assistant should pronate forearm. This manoeuvre allows the posterior interosseous nerve *(the deep branch of the radial nerve)* to be away from the incision line by approximately 1cm. The joint capsule should be incised above the lateral collateral ligament avoiding any damage to its attachment, which is situated at the central point of curvature of the humerus capitulum from the lateral side.

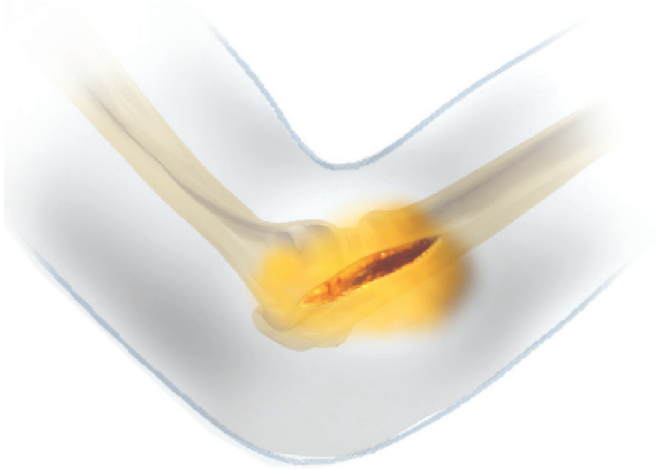
Next, incise the joint capsule and the proximal part of the annular ligament unless it is damaged and the incision is unnecessary. In this manner the humeroradial joint is opened from the top, above the attachment of the lateral collateral ligament. Expose antero-lateral part of the humerus capitulum and the head of the radius. Due to radial head fracture, humerus capitulum is a better reference point than radial head, as the latter is often not directly visible in the operating field. From the joint side place Langenbecks's elevator up to the anterior surface of the distal humerus.

Next, place the second Langenbecks's elevator behind the remaining part of the radial head.

If fragments of the head are displaced, they should be found and removed. Keep the forearm pronated and incise the distal part of the annular ligament exposing the neck of the radius from the lateral side.

Carefully remove tissue with raspatory from lateral and anterior surfaces of the neck, place Langenbecks's elevator behind it. Remove all the remaining fragments of the radial head.

a

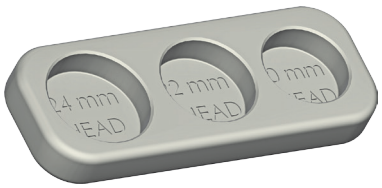


The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

V.2. PROSTHESIS IMPLANTATION

1 Measurement of the radial head diameter

Fragments of the radial head should be put together into the radial head bone trial **[40.5236.000]** fitting head diameter to a hollow in the trial. Do this on the operating table. Select appropriate prosthesis head on the basis of measured diameter.



40.5236.000

1

2 Resection of a radial head stump

Carefully rinse the joint with physiological saline. Using the resection guide, measure the distance from the cut radial neck stump to the humerus capitulum or from the cut radial neck stump to the proximal radial notch of the ulna *(in the case of using the stem [4.3690.000])*:

- The resection guide with cat. no. **[40.5242.010]** corresponds to 10mm of the heads of prostheses: **[7.3696.010]**, **[7.3697.010]**, **[7.3698.010]**, **[4.3692.010]**, **[4.3693.010]**, **[4.3694.010]**.
- The resection guide with cat. no. **[40.5242.012]** corresponds to 12mm of the heads of prostheses: **[7.3696.012]**, **[7.3697.012]**, **[7.3698.012]**, **[4.3692.012]**, **[4.3693.012]**, **[4.3694.012]**.
- The resection guide with cat. no. **[40.5242.014]** corresponds to 14mm of the heads of prostheses: **[7.3696.014]**, **[7.3697.014]**, **[7.3698.014]**, **[4.3692.014]**, **[4.3693.014]**, **[4.3694.014]**.

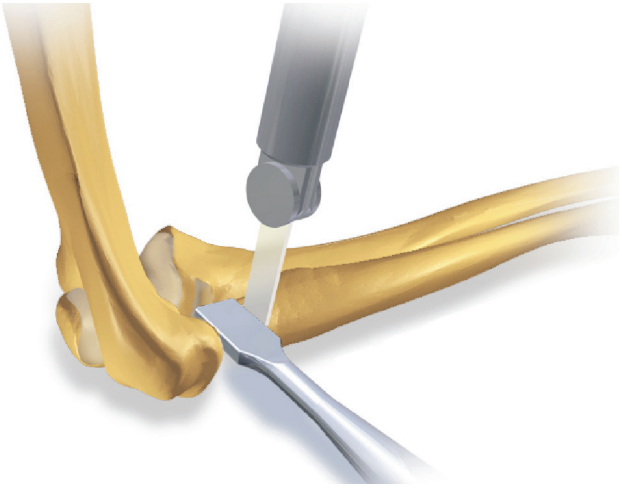
Cut the stump so it matches the closest size *(height)* of the radial head.

40.5242.010

40.5242.012

40.5242.014

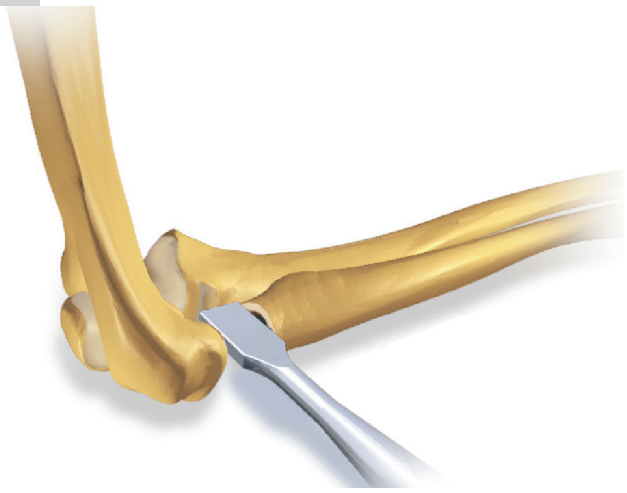
2



2a Establishing the size of prosthesis head

Measure the above-mentioned distance again. Choose the suitable size of the prosthesis head based on the measured distance, as well as on the measurement of removed radial head diameter.

2a



2b Extended fractures - Angular stem *(reconstructive)*

The fractures of radial head extended to fractures of the radial head's neck should be supplied with the angular stem **[4.3691.000]**, whose construction allows reconstruction of the anatomical neck deviation in respect to the bone axis.
In this case the neck should be resected just above the tuberosity of radius.
Choose the suitable size of the prosthesis head based on the measurement of removed radial head and available trials.

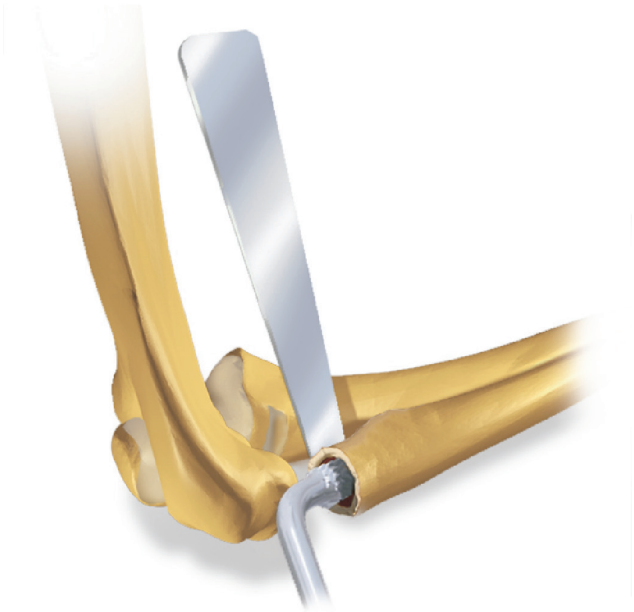
3 Preparation of a medullary canal

Insert an elevator behind the neck of the radius and identify the bone marrow canal using a *"frim"* or a thin Wolszczan's chisel.
Next, using a reamer, a curette, and finally a rasp **[40.5232.000]** prepare the canal for implantation of the stem of the prosthesis. The canal should be wider by 0.5mm at both sides of the stem and longer than the stem by at least 0.5cm.
Plug the marrow canal with a bone block excised from the spongy portion of the removed radial head.
Carefully rinse the canal with saline.

If the angular stem is used, penetrate the bone marrow with the rasp **[40.5232.000]** to the marker signed RECON.
If the standard stem is used, penetrate the bone marrow with the rasp to the end of its filing part.

40.5232.000

3

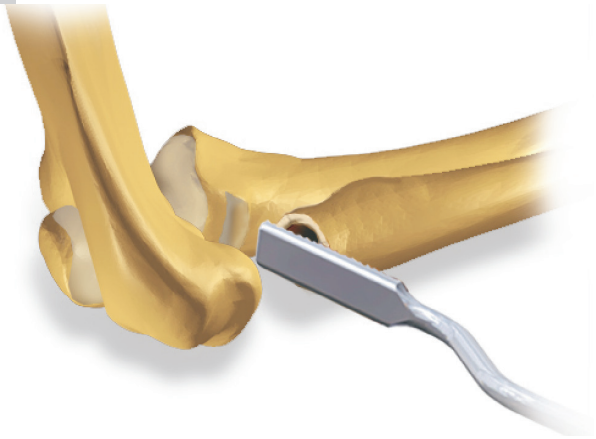


4 Preparation of the frontal surface

Using a rectangular curved file **[40.5233.000]** make the stump of the radial neck smoother.

40.5233.000

4

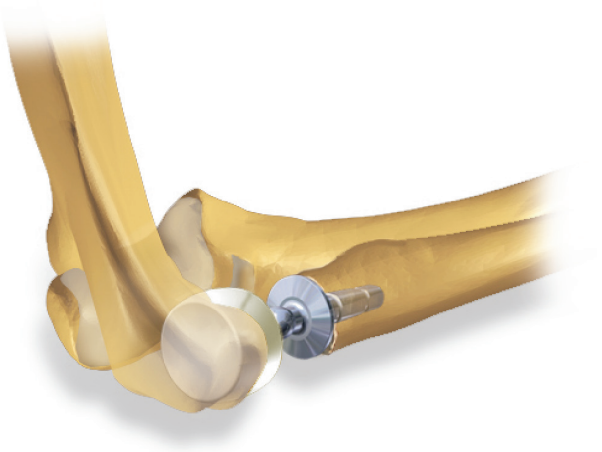


If the angular stem **[4.3691.000]** is used, omit the 5a and 5b steps, because collarless stem construction makes it impossible to carry the steps out.

5a Implantation test

First insert the stem **[4.3690.000]** into previously prepared canal of the radial neck, and then put on it an appropriate trial of prosthesis head. Select diameter and height of the trial on the basis of: measured diameter of radial head *(see step 1)* and the distance from the cut radial neck stump to the humerus capitulum or to the proximal radial notch of the ulna *(see step 2)*.

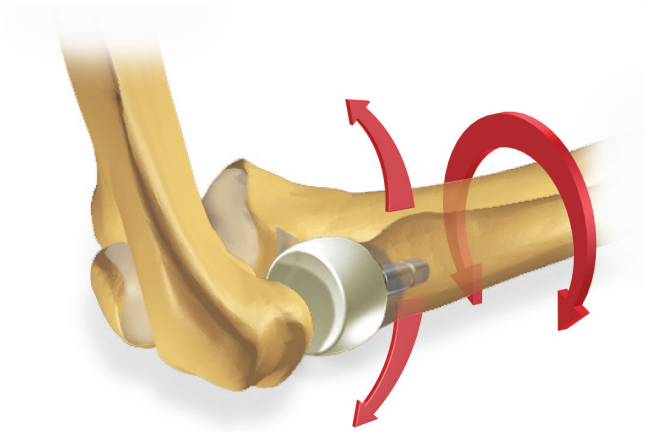
5a



5b Assessment of the elbow joint stability

The collar of the stem should rest perfectly on the stump of the radial neck.
Check the joint stability and whether the head of prosthesis trial centers well on the humerus capitulum. Check the range of movement of the elbow joint: flexion, extension and rotation.

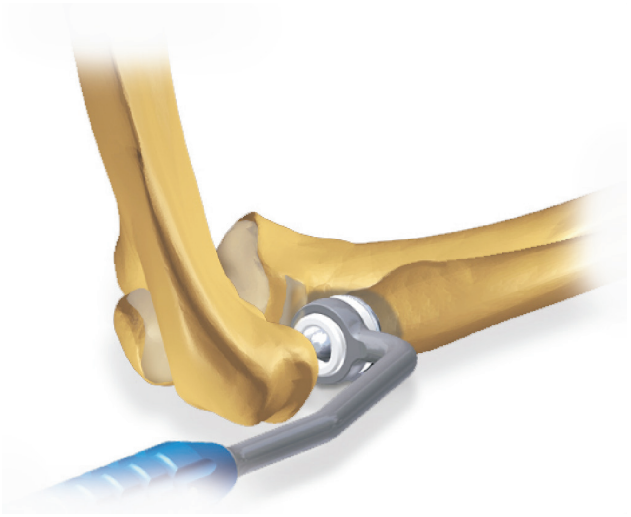
5b



6 Implantation of the prosthesis final components

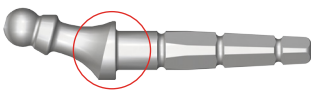
Carefully rinse the joint and then implant the stem **[4.3690.000]**. Using the rhb prosthesis stem impactor **[40.5234.000]**, keep pushing the stem to the radial head stump until the bone cement has bound.
Next, put on the stem the appropriate prosthesis head. To put the head of the implant on the stem, slightly *"stick out"* the radial bone sideways. The step may be performed without releasing the attachment of the lateral collateral ligament complex since the intramedullary part of the stem of the implant is relatively short *(facilitated implantation)*. It is possible thanks to bipolar structure of the implant.

6



During the implantation of the angular stem, position the stem in line with anatomical radial neck deviation, i.e.:
• set the forearm in the intermediate rotation *(0°)* - the abducted patient's thumb is then directed forward.
• insert the angular stem so that the curved proximal end of the stem is facing the direction indicated by the patient's thumb *(while still in the intermediate rotation of the forearm)*.

Then softly push the stem until the bone cement has bound. Due to the collarless structure, immerse the stem in the cement up to the visible limiter.



40.5234.000

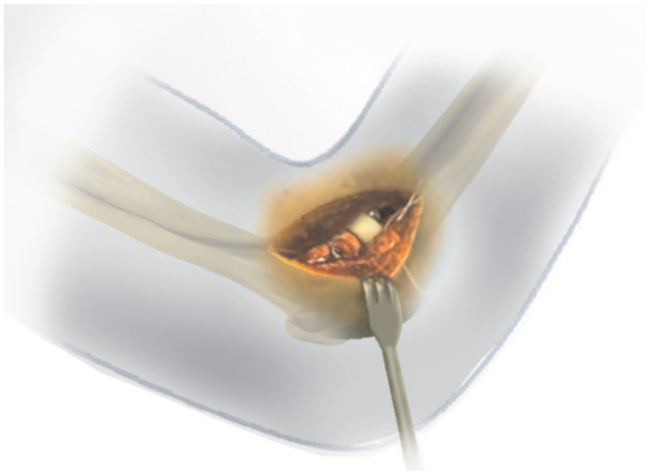
The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

7 Final stage

Rinse the joint and apply Redon's drain.

It is recomended to put 2 mattress sutures on previously partially released attachment of the brachioradialis muscle.
Next, put on 2 or 3 sutures on the annular ligament; if it is seriously injured then stitch the articular capsule trying to *"close"* the joint. Sutures on fascia, subcutaneous tissue, and skin finish the operative procedure.
Put on a *"cocoon"* type sterile dressing with a thick layer of cotton and elastic bandage. There is no need to apply a plaster cast.
Put the limb in an elevated position and check the blood supply, sensation and fingers movement after the procedure.

7



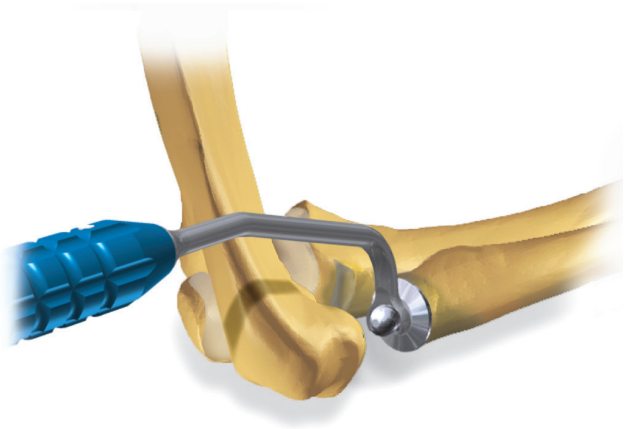
V.3. PROSTHESIS REMOVAL

8 In the case of infection of soft tissues around the implant it is recommended to remove the implant without performing reimplantation.

Having reached the humerorradial joint remove the prosthesis head, and then remove the stem with the use of rhb prosthesis stem holder **[40.5235.000]**. This instrument allows for grabing and pulling with a minimum force, with a simultaneous tapping with a mallet into the curved part. At the same time use a thin chisel to remove the bone cement from the space between the collar and the stump of radial neck *(the surgeon decides about the tool used during the procedure)*.

Pay special attention not to damage the radius and other structures of the elbow joint. After stem removal from the marrow cavity remove completely the bone cement using a special hook and chisel *(a surgeon performing the **operation** chooses an appropriate tool)*.

8



40.5235.000

The above description is not detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

V.4. PROSTHESIS REIMPLANTATION

In the case of:
- damage to the prosthesis head or stem,
- aseptic prosthesis loosening and/ or disconnection of its components,

the re-implantation of all the prosthesis elements *(stem with head)* is allowed.

Re-implantation indications

- joint instability *(valgization mainly)*,
- distal radioulnar joint *(DRUJ)* subluxation,
- excessive valgus of the elbow joint resulting from lack of radial head *(previous prosthesis removal or resection)*

Contraindications for re-implantation are contained in the instructions for use for radial head prosthesis – chapter CONTRAINDICATIONS.

Implanted radial head prosthesis which stays in the body for a period of 3 to 6 months, enables the proper healing of damaged tissues *(prosthesis functions as a spacer)*. After this period, when there is a need to remove the prosthesis, there is little chance of the occurrence of the complications such as: joint instability or valgus of the elbow joint, and/ or distal radioulnar joint *(DRUJ)* subluxation.

If the joint, despite the absence of radial head:
- is painless,
- achieves a functional range of motion,
- is stabile,
- shows no clear axis disorder and there are no symptoms associated with the wrist,

there is no direct indications for re-implantation of the radial head prosthesis.

GB

ISO 9001/ ISO 13485

CE

Manufacturer: ChM sp. z o.o.
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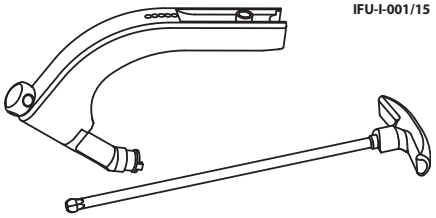

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INSTRUCTIONS FOR USE
REUSABLE ORTHOPAEDIC AND SURGICAL INSTRUMENTS

DESCRIPTION AND INDICATIONS

Instruments manufactured by **ChM** sp. z o.o. are mainly made of steel, aluminium alloys and plastics used in medicine and in accordance with the applicable procedures.

Each medical instrument is exposed tooccurrence of corrosion, stains and damage if not treated with special care and according to recommendations provided below.

The use of instruments in accordance with their intended purpose prolongs their usability.

Instrument's durability is limited and highly related to the manner and frequency of its usage.

The unit package contains one piece of the product in non-sterile condition. The welded clear foil sleeve is typical packaging material. The products may also be supplied as complete sets *(arranged on trays and placed into specially designed sterilization containers)*.

This Instructions For Use is attached both to the unit package and to the instrument set as well.

The packaging is equipped with the product label. The label contains:
- **ChM** logo and the manufacturer's address,
- name, size and catalogue number of the device *(REF)*, e.g.: 40.XXXX.XXX,
- production batch number *(LOT)*, e.g.: XXXXXXX,
- NON-STERILE sign: indicates non-sterile product,
- information symbols *(described in the footer of this Instructions For Use)*.

Depending on the size or type of the product, the following information may be marked on its surface: **ChM** logo, production batch no. *(LOT)*, catalogue no. *(REF)*, type of material and device size.

MATERIALS

Devices are produced of corrosion-resistant steel. The protective layer *(passive layer)* against corrosion is formed on the surface of the steel due to high content of chromium.

Devices produced of aluminium are mainly stands, palettes, cuvettes and some parts of instruments such as handles of screwdrivers, awls or wrenches, etc. The protective oxide layer, which may be dyed or stays in natural colour *(silvery-grey)*, is formed on the aluminium as an effect of electrochemical treatment on its surface.

Devices made of aluminium with processed layer have a good corrosion resistance.

The contact with strong alkaline cleaning and disinfecting agents, solutions containing iodine or some metal salts, due to chemical interference with the processed aluminium surface, shall be avoided.

Devices are mainly manufactured out of the following plastics: PPSU *(Polyphenylsulfone)*, PEEK *(Polyetheretherketone)* and teflon *(PTFE - Polytetrafluoroethylene)*.

The above mentioned materials can be processed *(washed, cleaned, sterilized)* at temperatures not higher than 140°C, they are stable in aqueous solution of washing-disinfecting agents with pH values from 4 to 10.8.

If the material of the device cannot be specified, please contact ChM sp. z o.o. representative.

WARNINGS AND PRECAUTIONS

1. Reusable orthopaedic and surgical instruments are intended for use in operating room conditions only by skilled and trained medical professionals, specialists in surgery, who are familiar with their use and application.
2. The surgeon should be familiar with all components of the device before use and should personally verify if all components and devices are present before the surgery begins.
3. Prior to the device usage and before procedure begins, all components of instruments should be carefully inspected for proper functioning and condition.Blades of all cutting edges should be sharp and undamaged. Replace any damaged accessory immediately. Employing bent or damaged surgical instruments in surgery is not allowed.
4. Tissue structures close tooperative site must be protected.
5. Contact of the instrument with metal operating equipment, retractors or other devices may cause damage that necessitates intraoperative replacement of that instrument.
6. Do not apply excessive force when using the instrument – it may lead to its faulty operation and, in consequences, to permanent damage.
7. While rare, intraoperative fracture or breakage of the instrument can occur. Instruments which have been subjected to extensive use or extensive force are more susceptible to fractures, depending on care taken during surgery and the number of procedures performed.
8. In the case of breakage and presence of instrument fragments in the patients' body, remove and dispose of them following the appropriate protocol of the unit.
9. In the case of suspected or documented allergy or intolerance to metallic materials, surgeon shall find out if the patient develops allergic reaction to the instrument material by ordering appropriate tests.
10. Improper or careless handling of the instruments and related chemical, electrochemical and physical damage may adversely affect the corrosion resistance and shorten the life of the instruments.
11. Reusable orthopaedic and surgical instruments are intended only for specific procedures and must be used strictly according to their intended purpose. Use of instruments not in accordance with their intended purpose may lead to malfunction, accelerated wear and – in consequences – damage of the instrument.
12. It is extremely important to follow the calibration deadline which is permanently marked on the torque instruments *(see CALIBRATION)*. Use of a torque instrument with an overstepped calibration date may lead to potential injury, implant or device damage, or loss of correction.

If there appear any irregularities in device operation, e.g. due to heavy usage, prior to next calibration date, the instrument should be immediately sent to the manufacturer for its re-calibration.

CLEANING, DISINFECTION AND STERILIZATION

Prior to use of a non-sterile device the following rules apply:

- Before use, the device must undergo cleaning, disinfection and sterilization procedures. It is recommended to use an automated procedure *(washer-disinfector)* for cleaning and disinfecting.
- Effective cleaning is a complicated procedure depending on the following factors: the quality of water, the type and the quantity of used detergent, the techniques of cleaning *(manual, ultrasound, with the use of washing/disinfecting machine)*, the proper rinsing and drying, the proper preparation of the instrument, the time, the temperature and carefulness of the person conducting this process.

Preparation for cleaning

After removing the product from its original packaging and before each cleaning, remove possible surface contamination using a disposable cloth, paper towel or plastic brushes *(nylon brushes are recommended)*.

It is not permitted to use brushes made of metal, bristles or materials which can cause damage to the device.

Cleaning and disinfection process

Chosen detergents and disinfectants must be suitable and approved for use with medical devices. It is important to follow the instructions and restrictions specified by the producer of these detergents.

CAUTION:

To avoid product damage (pitting, rust), **DO NOT** *use highly aggressive agents (NaOH, NaOCl), salt solutions and other unsuitable cleaning agents. It is recommended to use aqueous solutions of washing-disinfecting agents with a pH value between 7 and 10.8.*

Manual cleaning

- Apply cleaning agent solution to the product surfaces with careful brushing. A suitable brush must be used for cleaning holes.
- If applicable, ultrasonic cleaning may be used. The ultrasonic bath must be prepared according to the manufacturer's instructions.
- Next rinse thoroughly under running water. It is recommended to use demineralized water.
- Visually inspect the entire surface of the device for damage and contaminants. Damaged products must be removed. For contaminated products, the cleaning process should be repeated.

CAUTION:

- *Never use metal brushes, files or sponges for contaminants removal.*
- *Rinse thoroughly and carefully. Sterile demineralized water facilitates water spots removal from the instrument's surface.*
- *Instruments with cannula should be blown through using compressed air gun, or air supplied from a syringe.*
- *If the accumulated in the cannula material cannot be removed in accordance with the instructions, the device should be considered at the end of its useful life and should be disposed of in accordance with the facility procedures and guidelines.*

Cleaning with washer-disinfector

The device should undergo a process of machine washing in the washer-disinfector *(use washing-disinfecting agents recommended for medical devices)*.

CAUTION: The cleaning/disinfecting appliances should be compliant with requirements specified in ISO 15883.

Procedure of washing in the washer-disinfector shall be performed according to internal hospital procedures, recommendations of the washing machine manufacturer, and instructions for use prepared by the washing-disinfecting agents manufacturer.

Disinfection should be carried out at 90° *(soak for at least 10 minutes in demineralized water)* without the use of detergents.

Drying

Drying of the device must be performed as a part of the cleaning/ disinfection process.

Inspection

Before preparing for sterilization, all medical devices should be inspected.

Generally, visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/or corrosion. Particular attention should be paid to:

- soil traps such as mating surfaces, hinges, recesses, instruments shafts,
- holes, cannulations,
- places where soil may be pressed during use,
- cutting edges should be checked for sharpness and damage,
- special care should be taken to inspect the instruments for complete dryness prior to their storage.

Functional checks should be performed where possible:

- mating devices should be checked for proper assembly,
- all reusable orthopaedic and surgical instruments should be checked for straightness.

CAUTION:

The **ChM** *sp. z o.o. does not define the maximum number of uses appropriate for re-usable medical instruments. The life of these devices depends on many factors including the method, way and duration of each use, and the handling between uses.*

Inspection and functional testing of the device must be carried out before each use. In the case of identified damage, the instrument must not be used again.

ATTENTION! The manufacturer does not recommend using any preservatives on surgical and orthopedic devices.

Packaging

The product supplied non-sterile must be repacked in a packaging intended for a specific sterilization method that meets the requirements of ISO 11607-1 and is marked with CE sign. The packaging procedure must be performed in controlled purity conditions. The product must be packed in such a way that during removal from the package to be used, there is no risk for its contamination. Sterilization package is designed to maintain the sterility of medical devices after the sterilization process and during their storage prior to use.

Sterilization

Before each sterilization procedure and application, the device has to be controlled. The device is to be efficient, without toxic compounds like residues after disinfection and sterilization processes and without structure damage *(cracks, fractures, bending, peeling)*. Remember that sterilization is not a substitute for cleaning process!

Disinfected, washed, and dried device shall undergo the sterilization process in accordance with the client procedures. The recommended method of sterilization is vacuum-type steam sterilization *(with water vapor under overpressure)*:

- temperature: 134°C,
- minimum exposure time: 7 min,
- minimum drying time: 20 min.

CAUTION:

- *Sterilization must be effective and in accordance with requirements of the EN 556 standard which means that theoretical probability of presence of a living microorganism is less than 1/10⁶ (SAL=10⁻⁶, where SAL stands for Sterility Assurance Level).*
- *Device must not be sterilized in the package in which it was delivered, except specially designed sterilization containers.*
- *Validated sterilization methods are allowed.*
- *Sterilization of surgical instruments shall be carried out using appropriate equipment and under the conditions that conform to applicable standards.*
- *Devices manufactured out of plastics (PPSU, PEEK, PTFE) may be sterilized by any other available sterilization method validated in the centre but the sterilization temperature is not to be higher than 140°C.*

Durability and strength of instruments to a considerable degree depend on how they are used. Careful usage consistent with intended use of the product protects it against damage and prolongs its life.

STORAGE

The devices should be properly stored. When storing surgical instruments it is recommended that they never be stacked together. It may lead to damage of cutting edges *(nick or dull)* and/or initiation of corrosion centers. Instruments should be stored in dark, dry room, if possible – in suitable storage racks and placed into specially designed sterilization containers.

CALIBRATION

1. Regular calibration is required in case of torque wrenches, handles and connectors. Torque instruments are factory-calibrated, the nominal torque of a calibrated instrument is marked on the device *(e.g. 4 Nm)*.

   To maintain a high level of safety and accuracy of operation of a torque instrument, it is necessary to follow the calibration deadline which is marked on the device.
2. The calibration is conducted by the manufacturer – **ChM** sp. z o.o. Any unauthorized modifications of the structure or default, factory settings may lead to potential injury or device damage and are forbidden.

If this instructions appears unclear, please contact the manufacturer, who shall provide all required explanations.

Updated INSTRUCTIONS FOR USE are available on the following website: **www.chm.eu**

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SYMBOL TRANSLATION • OBJAŚNIENIA SYMBOLI • ПОЯСНЕНИЕ ОБОЗНАЧЕНИЙ • EXPLICACIÓN DE LOS SÍMBOLOS • SYMBOLERKLÄRUNG • SYMBOLY PŘEKLADY • TRADUZIONE SIMBOLI

	Do not reuse • Nie używać powtórnie • Не использовать повторно • No reutilizar • Nicht wiederverwenden • Nepoužívejte opakovaně • Non riutilizzare
STERILE	Do not resterilize • Nie sterylizować ponownie • Не стерилизовать повторно • No reesterilizar • Nicht resterilisieren • Nepoužívejte resterilizaci • Non risterilizzare
	Do not use if package is damaged • Nie używać jeśli opakowanie jest uszkodzone • Не использовать при поврежденной упаковке • No utilizar si el envase está dañado • Nicht verwenden falls Verpackung beschädigt ist • Nepoužívejte, pokud je obal poškozen • Non utilizzare se la confezione è danneggiata
	Consult Instructions for Use • Zajrzyj do instrukcji używania • Обратитесь к инструкции по применению • Consultar instrucciones de uso • Siehe die Gebrauchsanweisung • Řiďte se návodem k použití • Consultare le istruzioni per l'uso
NON STERILE	Non-sterile • Niesterylny • Не стерильно • No estéril • Unsteril • Nesterilní • Non sterile
	Caution • Ostrzeżenie • Осторожно • Advertencia • Vorsicht • Varování • Attenzione leggere il foglietto illustrativo
STERILE R	Sterilized using irradiation • Sterylizowany przez napromienianie • Радиационная стерилизация • Esterilizado mediante radiación • Sterilisiert durch Bestrahlung • Sterilizovat zářením • Sterilizzato mediante irradiazione
STERILE VH202	Sterilized using hydrogen peroxide • Sterylizowany nadtlenkiem wodoru • Стерилизован перекисью водорода • Esterilizado con peróxido de hidrógeno • Sterilisiert mit Wasserstoffperoxid • Sterilizováno s peroxidem vodíku • Sterilizzato mediante perossido di idrogeno
REF	Catalogue number • Numer katalogowy • Номер по каталогу • Número de catálogo • Katalognummer • Katalogové číslo • Numero di catalogo
LOT	Batch code • Kod partii • Код партии • Código de lote • Chargennummer • Číslo šarže • Codice del lotto
Mat:	Material • Materiał • Материал • Material • Materiál • Materiál • Materiale
Qty:	Quantity • Ilość • Количество • Cantidad • Menge • Množství • Quantita'
	Use by • Użyć do • Использовать до • Usar antes de • Verwenden bis • Použijte do • Da utilizzare entro il

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CE 0197
ISO 9001
ISO 13485